

COPY

REMARKS

Reconsideration of the present application in view of the following remarks is respectfully requested. The application includes claims 72-135 and 249-361, pending and under consideration. No amendments to the claims are being made in this Response.

In the outstanding Action, claims 72-135 and 249-361 were pending, and claims 72-135 and 249-361 stand rejected. In addition, the “amendment filed 12/17/04 and the amendment files [sic] 12/8/06” are objected to under 35 U.S.C. §132 on the grounds that they introduce new matter into the disclosure. Reconsideration of the present application in view of the remarks set forth herein is respectfully requested.

At the outset, Applicants note that the outstanding Action merely repeats the same grounds for rejection claims and objecting to claim amendments that were asserted in the prior Action, but fails to provide grounds upon which the rejections and objections can properly be repeated. Specifically, the Manual of Patent Examining Procedure (“MPEP”) makes clear that if an Examiner repeats a rejection, it is incumbent upon the Examiner to “take note of the applicant's argument and answer the substance of it.” MPEP §707.07(f). This same subsection further instructs the Examiner to “provide explanation as to non-persuasiveness.” The outstanding Office Action, however, does not even acknowledge, nor does it answer the substance of any of Applicants’ previous arguments, nor has it provided any explanation as to non-persuasiveness. The Action simply repeats the rejections.

Moreover, the outstanding Office Action indicates, on page 6, that, “Applicant’s arguments with respect to claims 72-371 [sic] have been considered but are moot in view of the new ground(s) of rejection.” However, the outstanding Action includes no new ground(s) of rejection. Rather, the same grounds for rejection of claims as having inadequate written description support and as constituting new matter have been repeated. Because the Examiner has not responded to the substance of Applicants’ extensive arguments in the manner required by MPEP §707.07(f), Applicants submit that the outstanding Office Action provides insufficient grounds for repeating the same rejections and objections.

Applicants continue to believe that the previously-submitted arguments support the patentability of the pending claims, and respectfully requests an indication that, each of

pending claims 72-135 and 249-361 is in condition for allowance. If the Examiner continues to maintain any rejection, Applicants request that the Examiner withdraw the finality of the outstanding Action and issue another Office Action "tak[ing] note of the applicant's argument and answer[ing] the substance of it," and "provid[ing] explanation as to non-persuasiveness."

Interview Summary re: Discussion with the Examiner April 30, 2007.

In view of the deficiencies of the outstanding Office Action, the undersigned contacted the Examiner by telephone to point out that the Action does not acknowledge Applicants' prior arguments, answer the substance of the arguments or provide any explanations regarding why the arguments were deemed non-persuasive. On April 30, 2007, the Examiner and the undersigned discussed these issues, and the Examiner thereafter mailed an Interview Summary dated May 7, 2007. The interview and the Interview Summary fail to overcome the deficiencies in the outstanding Office Action, however, because the Examiner's comments in the interview and in the Interview Summary simply reiterate the same grounds for rejection stated in the Office Action, but do not answer the substance of Applicants' arguments or provide any explanation as to how or why the arguments are considered to be non-persuasive. Moreover, even if the Examiner had provided supplemental comments in the interview and the Interview Summary to answer the substance of Applicants' arguments, they were not provided until May 7, 2007, and should at the very least set a new time period for Applicants to respond.

Applicants provide the following additional remarks in response to the statements in the Interview Summary:

- (1) In the Interview Summary, the Examiner asserts that, "Applicant was advised that the 102e rejection was valid because the new matter in the claims did not get the earliest priority date. The new matter was provided with the priority date of the filing of the current application." In reply, Applicants traverse this assertion, as discussed more fully below, on the grounds that the pending claims are entitled to the benefit of priority to the prior-filed priority documents that antedate the cited references.
- (2) In the Interview Summary, the Examiner asserts that, "The applicant was also informed that the examiner maintains [sic] the 112 new matter rejections are valid because the term flattened does not provide support for the term non-arcuate." In

reply, Applicants submit that (i) this assertion does not address the substance of Applicants' prior arguments or constitute any explanation of why the Examiner believes those arguments are non-persuasive, but rather only re-states the rejection with no explanation, and (ii) the rejection of claims on this assertion is improper for all of the reasons previously argued, and reiterated hereinbelow.

- (3) In the Interview Summary, the Examiner asserts that, "The applicant was also informed that the broad limitation requiring the dowels wach [sic] have a width less than approximately 1/2 the width of the adjacent vertebral body is not supported by a single figure showing dowels that small. The specification doesn't limit the size of the dowels in this fashion because they would clearly work in a vertera [sic] even if they were sized to be larger than half of its width by overlapping their centers."

In reply, Applicants submit that the first statement is incorrect because, as pointed out by Applicants multiple times in the course of prosecution of this case, Figures 6, 8 and 9 of the present application, as originally filed, clearly show dowels having a width less then approximately 1/2 the width of the adjacent vertebral body. This is thoroughly discussed at least at the following locations: (i) page 15 of Applicants' response dated December 13, 2004, (ii) pages 15-17 and 19 of Applicants' response dated September 14, 2005, and (iii) pages 39-41 of Applicants' response dated December 4, 2006.

Moreover, the second statement quoted above is irrelevant to the present analysis. As Applicants have pointed out previously, and as reiterated hereinbelow, proper written description support for claimed subject matter is not negated by the fact that the specification also describes embodiments outside the scope of a pending claim. Any rule that were to make this reasoning a proper basis for rejecting a claim, would forbid an Applicant from presenting claims having varying scope (i.e., dependent claims). With further reference to dependent claims as an example, it is an inherent characteristic of dependent claims that they are narrower than the claim(s) from which they depend, and thereby necessarily omit embodiments that are described in the specification and that "would clearly work" even though they are not encompassed by the narrower claim. This reasoning, therefore, cannot support this claim rejection.

Reiteration of Prior Arguments

For the convenience of the Examiner, Applicants have copied below the arguments submitted on December 4, 2006, in response to the prior Office Action dated August 2, 2006.

Additional remarks are also added hereinbelow in italics as supplemental information.

Reiteration of prior arguments regarding support in the specification as filed for the wording "...said upper and lower portions being non-arcuate along at least a portion of the length of the implant...":

[C]laims 72-134 are rejected in the outstanding Action under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In support of this rejection, the Action asserts that the specification does not support the recitation in claims 72, 91 and 111 of "...said upper and lower portions being non-arcuate along at least a portion of the length of the implant..." In traversal of this rejection, Applicant submits that a person of ordinary skill in the art at the time of the present application would have understood, based upon the originally-filed specification, that Applicant was in possession of the claimed subject matter. For example, the specification describes a modification to the embodiment depicted in Figs. 4 and 5 whereby the upper and lower portions are flattened. This embodiment with flattened upper and lower portions is itself an embodiment in which upper and lower portions are non-arcuate along at least a portion of the length of the implant. Applicant would draw the Examiner's attention to paragraph 78 of the published application (Application Publication No. 2004/0073309), which states the following:

In some embodiments, the wall 506 may include upper and lower flattened portions to stabilize the dowel by neutralizing any rotational torque that may be induced by pressure on the sidewall. This could be achieved by reducing the height H of the sidewall 505 and ends 501, 502 by filing or like means.

In view of the description in the specification of an embodiment as depicted in Figs. 4 and 5, but with upper and lower flattened portions, Applicant submits that the specification provides solid written description support for the subject matter recited in the pending claims under 35 U.S.C. § 112, first paragraph. Applicant therefore respectfully requests withdrawal of this rejection.

At page 4 of the Action the Examiner makes an analogy to a road having a flattened surface and that curves to the left or right, and states that such a road would be considered flattened and arcuate. In reply, Applicant submits that the existence of alternative embodiments that are not representative of a subject claim is not a valid reason to reject a claim under Section 112, first paragraph. The specification clearly describes an embodiment having upper and lower portions that are non-arcuate along at least a portion of the length of the implant, and this claim therefore satisfies the written description requirement of Section

112, first paragraph. Moreover, Applicant submits that a spacer having a flattened side and that bends along its length would also be understood by a person skilled in the art at the time of the present application to be contemplated by the wording "said upper and lower portions being non-arcuate along at least a portion of the length of said implant."

In addition to the above, the following is a copy of Applicants' prior argument on this point, as set forth in the prior response dated September 14, 2005, at pages 17-19:

[T]he specification of the subject application describes ... embodiments of implants including implants having a wall including "upper and lower flattened portions . . . achieved by reducing the height H of the sidewall 505 and ends 501, 502" of the implant. (See paragraph 78, lines 1-5). A cross section of such an implant embodiment would clearly show the flattened portions extending along the length of the implant between the ends 501, 502. Thus, Applicant is unclear as to the statement in the Office Action that "there would be a portion that is 'arcuate'." The only interpretation that would be consistent with this statement would be taking a transverse or lateral cross section of the implant with reference given to the curved sides extending between the upper and lower flattened portions. However, while the sides of the implant would be arcuate, the upper and lower flattened portions would clearly not have an arcuate configuration. If the rejection of claims 72-134 under 35 U.S.C. §112 is maintained, the Applicant respectfully requests clarification regarding the statement set forth in the Office Action that "there would be a portion that is 'arcuate'."

Furthermore, although the specification does not specifically describe the upper and lower portions as being "non-arcuate", the Applicant submits that the language recited in the claims need not be described in the specification using precisely the same terminology. Indeed, when claiming an invention, "there is no in haec verba requirement". MPEP §2163, I-B. Instead, "added claim limitation must be supported in the specification through express, implicit, or inherent disclosure." Id. Furthermore, the standard for sufficiency of support is whether the disclosure reasonable conveys to the artisan that the inventors had possession of the subject matter at the time of filing the application. MPEP §2163.02.

With the above-mentioned principles in mind, the Applicant submits that the phrase "said upper and lower portions being non-arcuate", as recited in independent claims 72, 91, 111 and 134, is sufficiently supported by the phrase "upper and lower flattened portions" set forth in paragraph 78 of the specification. Specifically, the term "flattened" is defined in Webster's New World Dictionary (3rd College Ed.) as "having little or no depression or elevation". Additionally, the term "arcuate" is defined as "curved" or "arched". The term "non-arcuate" would thereby logically be defined as having little or no curvature or arch. As a result, "non-arcuate" falls within the definition of "flattened" in that a feature described as "non-arcuate" would have "little or no depression or elevation". Therefore, the Applicant submits that the term "flattened" implicitly or inherently supports the term "non-arcuate". Moreover, the Applicant submits that the standard for sufficiency of support is

satisfied in that disclosure of the phrase "upper and lower flattened portions" reasonably convey to a person of ordinary skill in the art that the inventors had possession of the claimed invention (i.e., an implant with the "upper and lower portions being non-arcuate") at the time of filing the application based, at least in part, on the disclosure set forth in paragraph 78 of the specification. For at least these reasons, the Applicant respectfully requests withdrawal of the rejection of independent claims 71, 91, 111 and 134 as failing to comply with the written description requirement of 35 U.S.C. §112, first paragraph.

If the Examiner is to repeat this rejection, Applicants submit that the Examiner must answer the substance of the above argument and provide explanations as to its non-persuasiveness. Such explanation must at the very least point out why the Examiner believes the cited rules to be inapplicable to this case. In the absence of such explanation, Applicants submit that this rejection should be withdrawn.

Reiteration of prior arguments regarding support in the specification as filed for the wording "Each of dowels 500 are illustrated as having a width less than approximately one-half of the width of the adjacent vertebral body":

The outstanding Action also includes a new matter objection, and an accompanying rejection under Section 112, first paragraph, with regard to the amendment filed 12/17/04 in which the following language was inserted into the specification: "Each of dowels 500 are illustrated as having a width less than approximately one-half of the width of the adjacent vertebral body." In support of the objection and rejection, the Examiner cites MPEP 2125 in support of the proposition that, "proportions of features in a drawing are not evidence of actual proportions when drawings are not to scale."

In traversal of the new matter objection and rejection, applicant submits that the identified subject matter would have been understood by a person of ordinary skill in the art at the time of the application to be reasonably taught by the descriptions provided in the application, and does not rely upon proportions depicted in the drawing. As such, the identified subject matter does not constitute new matter. In this regard, Applicant notes that MPEP 2125 also states that, "the description of the article pictured can be relied on, in combination with the drawings, for what they would reasonably teach one of ordinary skill in the art." (citation omitted). In the present case, the subject claims are directed to an

“interbody spinal implant.” The term “interbody” is understood by skilled artisans to mean located between the bodies of two adjacent vertebra. Paragraph 66 of the published version of the present application (Application Publication No. 2004/0073309) includes the following statement regarding the embodiment depicted in Fig. 6: “Bilateral placement of dowels 500 is preferred as shown in FIG. 6.” The term “bilateral” is well understood by skilled artisans to mean located on two sides of an axis. More specifically, in terms of interbody spinal implants, the term “bilateral” is understood to mean located on two sides of the central axis of the spinal column. Moreover, dowels 500 depicted in Fig. 6 do not overlap one another or cross the central axis of the vertebrae. Therefore, Fig. 6, which depicts an embodiment of the application involving bilateral placement of two dowels for operation as an interbody spinal implant, would be clearly understood to be characterized by each dowel having a width less than approximately one-half of the width of the adjacent vertebral body. This is the case irrespective of the sizes of the vertebral bodies, or the size proportions between the vertebral bodies and the spacers. Otherwise, the dowels could not be both bilateral and positioned between vertebral bodies. Applicant acknowledges the statement in the Action that, “it would be possible to place larger implants in the space that would overlap allowing for a width greater than half of the vertebral bodies width.” In reply, Applicant would again note that the proper inquiry under Section 112, first paragraph, is whether the specification describes the identified subject matter, not whether alternative embodiments might exist that differ from an exemplary embodiment specifically shown and described in the specification and recited in a given claim. A person skilled in the art at the time the application was filed would have understood, based upon the drawings and the accompanying descriptions, that the embodiment depicted in Fig. 6 includes two dowels that each has a width less than approximately one-half of the width of the adjacent vertebral body.

In view of the above, Applicant submits that support for the identified statement is clearly present in the application as filed, and does not rely upon any proportions of elements shown in a drawing. Applicant therefore respectfully requests that the objection to the specification and the rejection of claims based upon the identified specification amendment be withdrawn.

In addition to the above, the following is a copy of Applicants' prior argument on this point, as set forth in the prior response dated September 14, 2005, at pages 15-17 and 19:

The amendment filed with the U.S. Patent and Trademark Office on December 17, 2004 has been objected to under 35 U.S.C. §132 as introducing new matter into the specification. Specifically, in the previously-filed Response, paragraph 66 was amended to include the following sentence: "Each of dowels 500 are illustrated as having a width less than approximately one-half of the width of the adjacent vertebral body." The Applicant has submitted that the language added to paragraph 66 is supported by the subject application as originally filed. Specifically, Figure 6 and the corresponding description in paragraph 66 support the added language that the dowels 500 each have a width less than approximately one-half of the width of the adjacent vertebral body. Indeed, Figure 6 illustrates bilateral placement of a pair of spinal implants 500 in a side-by-side manner within the confines of the intervertebral disc space between adjacent vertebral bodies V. Since each of the spinal implants 500 defines a maximum width between the interior facing side 535 and the exterior facing side, and since the spinal implants 500 are positioned entirely within the intervertebral disc space, the maximum width of each of the spinal implants 500 must necessarily be less than approximately one-half of the width of the adjacent vertebral bodies, as recited in independent claims 72, 91 and 111 and as described in paragraph 66 of the subject application.

Nevertheless, the Office Action refers the Applicant to MPEP §2125 and to the case of Hockerson-Halberstadt, Inc. v. Avia Group Int'l for the proposition that drawings can not be scaled to provide evidence of the actual size or dimensions associated with the features shown in the drawings. The Applicant generally agrees with this proposition. However, the Applicant submits that Figure 6 in the subject application in not being scaled to determine the particular size or dimensions of the spinal implants 500, which was the issue specifically addressed in the Hockerson-Halberstadt decision. ("[I]t is well established that patent drawings . . . may not be relied on to show particular sizes if the specification is completely silent on the issue." 222 F.3d 951, 956 (Fed. Cir. 2000)). Instead, Figure 6 is being referred to in the context of illustrating the bilateral placement of a pair of spinal implants 500 in a side-by-side manner within the confines of the intervertebral disc space, and that such illustration would clearly convey to one of ordinary skill in the art that such bilateral placement necessarily dictates that the maximum width of each of the spinal implants 500 must be less than approximately one-half of the width of the adjacent vertebral bodies. The Applicant is not, however, relying on Figure 6 to establish measurements which evidence the actual size or dimensions of the spinal implants 500.

Moreover, as also cited in the Office Action, the In re Wright decision stands for the proposition that drawing figures can be relied on "for what they would reasonably teach one of ordinary skill in the art." 569 F.2d 1124 (CCPA 1977). Indeed, this is precisely what the Applicant is relying on Figure 6 to convey. Specifically, Figure 6 clearly illustrates and paragraph 66 correspondingly describes the bilateral placement of a pair of spinal implants 500 within the confines of the

intervertebral disc space, and such disclosure would reasonably convey to one of ordinary skill in the art that the maximum width of each of the spinal implants 500 must necessarily be less than approximately one-half the width of the adjacent vertebral bodies. Moreover, as set forth in MPEP §2163.06, "information contained in any one of the specification, claims, or drawings of the application as filed may be added to other part of the application without introducing new matter." (Emphasis added). Accordingly, the Applicant submits that it is proper to incorporate description into the specification based on information that the drawings would convey to one of ordinary skill in the art. As a result, the language added to the specification that each of the dowels 500 has a width less than approximately one-half of the width of the adjacent vertebral body (as shown in Figure 6) does not constitute new subject matter since the as-filed application clearly illustrates this feature of the claimed invention.

For at least the above-discussed reasons, the Applicant submits that the language added to paragraph 66 is properly supported by the subject application as originally-filed. Accordingly, withdrawal of the objection to the specification under 35 USC §132 is respectfully requested.

* * *

Finally, paragraph 4 of the Office Action also asserts that recitation of the phrase "less than approximately one-half of the width of the adjacent vertebral bodies" in independent claims 71, 91 and 111 constitutes new matter. The Applicants respectfully disagrees with this assertion for reasons similar to those discussed above with regard to the objection to the specification under 35 U.S.C. §132. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claims 71, 91 and 111 as reciting new matter.

If the Examiner is to repeat this rejection and the objection to the specification, Applicants submit that the Examiner must answer the substance of the above argument and provide explanations as to its non-persuasiveness. Such explanation must at the very least point out why the Examiner believes the cited rules and the cited judicial precedent to be inapplicable to this case or supportive of a different conclusion than that argued above. In the absence of such explanation, Applicants submit that this rejection should be withdrawn.

Reiteration of prior arguments regarding art rejections:

Claims 72-90, 134 and 135 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,258,125 to Paul et al. (hereafter, "the '125 patent") and

claims 91-133 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the '125 patent in view of U.S. Patent No. 6,530,955 to Boyle et al. (hereafter "the '955 patent").

In traversal of the art rejections, Applicant submits that neither of the references asserted in the Action qualifies as prior art to the pending claims under 35 U.S.C. § 102(e) or any other statutory provision. In this regard, Applicant would draw the Examiner's attention to the follow items of information:

- (1) the '125 patent was filed on July 30, 1999, and claims priority to a provisional patent application file August 3, 1998;
- (2) the '955 patent was filed on May 18, 2001 and is a divisional of a patent application filed June 8, 1999; and
- (3) the present application is a continuation application that claims priority to a string of prior patent applications in a line of cases extending back to a parent application filed June 3, 1997 (U.S. Patent Application Serial No. 08/867,963).

In view of the above, the pending claims of the present application are entitled to an effective filing date at least as early as June 3, 1997, for purposes of determining qualification of references as prior art. Neither the '125 patent nor the provisional patent application to which it claims priority was filed before June 3, 1997, and the '125 patent does not qualify as prior art to the present application under 35 U.S.C. § 102(e). Similarly, neither the '955 patent nor the prior patent application to which it claims priority was filed before June 3, 1997, and the '955 patent likewise does not qualify as prior art to the present application under 35 U.S.C. § 102(e).

Consequently, Applicant respectfully requests withdraw of the rejection of claims 72-90, 134 and 135 under 35 U.S.C. § 102(e) as being anticipated by the '125 patent and the rejection of claims 91-133 under 35 U.S.C. § 103(a) as being unpatentable over the '125 patent in view of the '955 patent.

While the Examiner states in the Interview Summary that Applicant is not entitled to its claim of priority due to the assertions in the Action pertaining to new matter and written description, Applicants traverse this position. Applicants submit that such assertions pertaining to new matter and written description should be withdrawn for the

COPY

reasons set forth above, and that the pending claims are entitled to the benefit of priority to the prior applications identified above, as asserted in the present application.

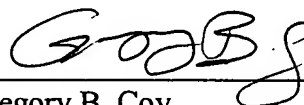
Closing

In view of the foregoing remarks, Applicants respectfully submit that none of the rejections or objections asserted in the Action can properly be maintained. Accordingly, reconsideration leading to withdraw of all the rejections and allowance of this application containing claims 72-135 and 249-361 are respectfully requested. In the alternative, if any rejection or objection is again repeated, Applicants respectfully request that the Examiner withdraw the finality of the outstanding Action and issue another Office Action taking note of the Applicants' arguments and answering the substance of them, and providing explanation as to non-persuasiveness, as required by MPEP §707.07(f).

If there are any remaining issues that can be addressed telephonically, the Examiner is invited to contact the undersigned to discuss the same.

Respectfully submitted,

By: _____



Gregory B. Coy
Reg. No. 40,967
KRIEG DeVAULT LLP
One Indiana Square
Suite 2800
Indianapolis, IN 46204-2079
Tel.: (317) 636-4341
Fax: (317) 238-6371

KD_IM-1017620_1.DOC